K110735

## 510(k) SUMMARY

### Pharos Life's Tända Max OTC System

AUG - 3 2011

**Contact Information:**

Pharos Life Corporation
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Cambridge, ON N3C 4N4
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Contact Person: Gordon Wehner

**Date Prepared:** March 15, 2011

**Device Name:** Tända Max OTC System

**Common or Usual Name:** Light Therapy Device

**Classification Name:** Laser Instrument, Surgical, Powered
(Laser surgical instrument for use in general and plastic surgery and dermatology)
Regulation No. 878.481 0
Product Code: GEX

**Predicate Devices:**

| Manufacturer | Device |
|---|---|
| Pharos Life | Tända Max System |
| LED Intellectual Properties | Anti-wrinkle Light |

**Intended Use / Indications for Use:**

The Tända Max OTC System is intended to be used for the treatment of wrinkles, rhytides, and fine lines in the periorbital region.

**Technological Characteristics**

The Tända Max OTC System is a modular system that offers simplicity in use and convenience. The system can operate while connected directly to an electrical outlet or can be used in cordless mode drawing upon its rechargeable batteries to deliver the treatment. The system components include the control unit, the treatment head, recharging stand, AC adapter, and goggles.

The Tända Max OTC System utilizes red light at 660 nm. The unit is applied directly to the skin to ensure consistent administration of light during each treatment. The surface that comes into contact with the skin has been selected to ensure the light is administered to the skin while providing a smooth surface for cleaning.

**Performance Data**

The Tända Max OTC System has been tested and found in conformance with the requirements of IEC 60601, including EMC and EMI. It has also been shown to comply with the requirements of IEC 60825, and ISO 10993 for biocompatibility. Tända Max OTC was developed under a Quality Management System conforming to ISO 13485;2003 and ISO 14971:2007. A clinical evaluation was successfully performed and the results of which are provided in this application.

**Substantial Equivalence**

The Tända Max OTC System is as safe and effective as the prescriptive Tända Max System and the Light for Wrinkles. The Tända Max OTC System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Tända Max OTC System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Tända Max OTC System is as safe and effective as its predicates. Thus, the Tända Max OTC System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room–WO66-G609
Silver Spring, MD 20993-0002

Pharos Life Corporation
% Hogan and Hartson
Mr. Johnathan S. Kahan
555 Thirteenth Street, NW
Washington, District of Columbia 20004

AUG - 3 2011

Re: K110735
Trade/Device Name: Tanda Max OTC System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHS
Dated: June 28, 2011
Received: June 28, 2011

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use Statement**

510(k) Number (if known): K110735

Device Name: Tända Max OTC

Indications for Use:

Tända Max OTC is intended for the treatment of wrinkles, rhytides, and fine lines in the periorbital region.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110735